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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,651	10/05/2001	Gary L. Bowlin	VCUIP-9 V1	2603
23599	7590	12/17/2002	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDRON BLVD. SUITE 1400 ARLINGTON, VA 22201			WEBER, JON P	
		ART UNIT	PAPER NUMBER	
		1651		

DATE MAILED: 12/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/970,651	BOWLIN ET AL.	
	Examiner Jon P Weber, Ph.D.	Art Unit 1651	
<b>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</b>			
<b>Period for Reply</b>			
<b>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</b>			
<ul style="list-style-type: none"> <li>- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</li> <li>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</li> <li>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</li> <li>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</li> <li>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>			
<b>Status</b>			
1) <input type="checkbox"/> Responsive to communication(s) filed on ____.			
2a) <input type="checkbox"/> This action is FINAL.                  2b) <input checked="" type="checkbox"/> This action is non-final.			
3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
<b>Disposition of Claims</b>			
4) <input checked="" type="checkbox"/> Claim(s) <u>1-22</u> is/are pending in the application.			
4a) Of the above claim(s) ____ is/are withdrawn from consideration.			
5) <input type="checkbox"/> Claim(s) ____ is/are allowed.			
6) <input type="checkbox"/> Claim(s) ____ is/are rejected.			
7) <input type="checkbox"/> Claim(s) ____ is/are objected to.			
8) <input checked="" type="checkbox"/> Claim(s) <u>1-22</u> are subject to restriction and/or election requirement.			
<b>Application Papers</b>			
9) <input type="checkbox"/> The specification is objected to by the Examiner.			
10) <input type="checkbox"/> The drawing(s) filed on ____ is/are: a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) <input type="checkbox"/> The proposed drawing correction filed on ____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.			
12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.			
<b>Priority under 35 U.S.C. §§ 119 and 120</b>			
13) <input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) <input type="checkbox"/> All b) <input type="checkbox"/> Some * c) <input type="checkbox"/> None of: 1. <input type="checkbox"/> Certified copies of the priority documents have been received. 2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. ____. 3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.			
14) <input type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application). a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.			
15) <input checked="" type="checkbox"/> Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.			
<b>Attachment(s)</b>			
1) <input type="checkbox"/> Notice of References Cited (PTO-892)		4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.	
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)		5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)	
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.		6) <input type="checkbox"/> Other: _____	

***Status of the Claims***

Claims 1-22 have been presented for examination.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I.      Claims 1-10 and 17-22, drawn to an engineered tissue comprising a suspension of cells, clotting agent and anticoagulated plasma and a method of making the same comprising mixing the components, classified in class 435, subclass 1.1 and 383+.
- II.     Claims 11-14, drawn to a matrix of clotting agent and plasma and method making the same, classified in class 530, subclass 380+.
- III.    Claims 15-16, drawn to a cancer therapy screening assay with engineered tissue, classified in class 435, subclass 40.51.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because other gelling methods for suspended cells could be used besides coagulated plasma such as simple gelatin or calcium alginate. The subcombination has separate utility such as a gel for drug delivery.

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Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the engineered tissue might be used as a temporary graft for damaged tissue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

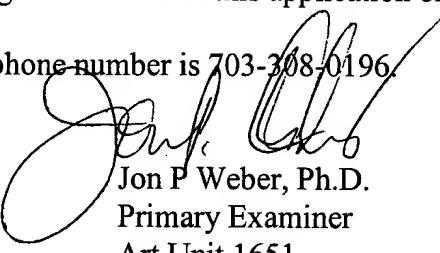
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for

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the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber, Ph.D.  
Primary Examiner  
Art Unit 1651

JPW  
December 16, 2002